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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,152	06/03/1999	MARK AARON EMALFARB	3123-4000US2	1956

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/284,152	Emalfarb et al.
Examiner	**Art Unit**
Christian L. Fronda	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____ .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-66 and 80-83* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *1* is/are allowed.

6) ☒ Claim(s) *2-66 and 80-83* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Claims 1-66 and 80-83 are under consideration.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2-66 and 80-83 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record.

Applicants' arguments filed on September 27, 2001, have been fully considered but they are not persuasive. Applicants' position is that the claims are not directed to "mutant cellulases", but to mutant *Chrysosporium* fungi and that the disclosure would reasonably convey to one of skill in the art that Applicants had possession of the invention.

Claims 2, 4, and 83 are directed to all possible mutant cellulases obtained from the genus *Chrysosporium*. The specification only discloses a mutant cellulase from a mutant strain of C-1 (see Example 14). There is no written description of any "mutant fungus" of the genus *Chrysosporium*. There is no disclosure of any particular structure to function/activity relationship in the mutant cellulase from a mutant strain of C-1. The specification also fails to describe additional representative species of these mutants by any identifying structural characteristics or properties for which predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 6-66 which depend from claims 2 or 4 are also rejected because they do not correct the defect of claims 2 or 4.

Claims 24, 36, 46, and 52 are directed to all possible nucleic acid sequences from a wild-type or mutant fungus of the genus *Chrysosporium* encoding a cellulase. The specification, however, does not provides a single representative species encompassed by the claim. There is no disclosure of any particular structure to function/activity relationship. The specification also fails to describe representative species of these nucleic acid sequences by any identifying

structural characteristics or properties other than the nucleic acid sequence encoding a cellulase used for treating cellulosic fibers or fabrics for which no predictability of structure is apparent. Given this lack of representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 25-29 and 32-35 which depends from claim 26 are also rejected because they do not correct the defect of claim 24. Claims 37-39 which depends from claim 36 is also rejected because they do not correct the defect of claim 36. Claim 47 which depends from claim 46 is also rejected because it does not correct the defect of claim 46. Claim 53 which depends from claim 52 is also rejected because it does not correct the defect of claim 52.

Claims 80-82 are directed toward all possible methods for generating mutant strains of the genus *Chrysosporium*. The specification, however, provides the following representative methods encompassed by the claim: exposure of spores to UV radiation, nitrous acid, N-methyl-N'-nitro-N-nitrosoguanidine, or 4-nitroquinoline-N-oxide. The specification fails to describe additional methods for generating mutant strains of the genus *Chrysosporium*. Given this lack of representative methods as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

4. Claims 2-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a mutant cellulase from a mutant strain of C-1(Example 14) and a cellulase from an isolated culture of *Chrysosporium lucknowense* Garg 27K having accession number VKM F-3500D; does not reasonably provide enablement for any mutant cellulase from any mutant fungus of the genus *Chrysosporium* for the reasons of record. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments filed on September 27, 2001, have been fully considered but they are not persuasive. Applicants' position is that specification reasonably provides enablement for any neutral and/or alkaline cellulase from any wild-type or mutant *Chrysosporium* species.

The nature and breadth of the claims encompass any mutant cellulase from any mutant fungus of the genus *Chrysosporium*. While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the specific mutation in the amino acid sequence of the claimed cellulase, i.e. deletion, insertion, substitution, and combinations thereof, which has a neutral and/or alkaline activity is lacking. Thus, searching for the specific amino acid residue(s) of the claimed cellulase to mutate which has neutral and/or alkaline cellulase activity is well outside the realm of routine experimentation and predictability in the art of success is extremely low.

The amount of experimentation to determine the specific mutation in the amino acid

sequence of the claimed cellulase is enormous. Such experimentation entails selecting a species of fungus from the genus *Chrysosporium*, isolating the neutral and/or alkaline cellulase from the selected species, preparing DNA libraries of the selected species, obtaining the DNA sequence encoding the cellulase from screening the DNA libraries, selecting a mutation to perform, i.e. deletion, substitution, insertion, or combinations thereof, mutating the DNA encoding the cellulase, express the mutated DNA encoding the cellulase in host cells, and screening for mutants which have neutral and/or alkaline cellulase activity. Since routine experimentation in the art does not include making and screening vast numbers of mutants for a cellulase having neutral and/or alkaline activity where the expectation of obtaining a desired cellulase having neutral and/or alkaline activity is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific mutation performed on the amino acid sequence of the claimed neutral and/or alkaline cellulase. Without such a guidance, the experimentation left to those skilled in the art is undue. Claims 6-66 are also rejected because they do not correct the defect of claims 2 or 4.

Conclusion

5. Claim 1 is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CLF

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